REMARKS

Claims 1-11 are pending, with claims 8-11 withdrawn from consideration as allegedly drawn to a non-elected invention. Applicant has reviewed the ground of rejection in the Office Action and respectfully traverse for the reasons that follow.

Regarding the restriction of claims 8-11 as claiming a separate invention from the elected group of claims, Applicant respectfully request reconsideration and withdrawal of this restriction. Claim 2 is directed to a method of diagnosing Crohn's disease by determining the presence or absence of IgA anti-OmpC antibodies. Restricted claim 8, which depends from claim 2, further includes detecting the presence or absence of IgA anti-I-2 polypeptide antibodies whereas restricted claim 10 further includes detection of the presence or absence of IgA anti-ASCA. Because both the elected and restricted claims include detection of the presence or absence of IgA anti-OmpC antibodies, a search of claim 2 would encompass the subject matter of claims 8 and 10 without requiring an undue burden on the Examiner. Further, claims 1 and 2 can be considered generic to the invention of claims 8-11 because the latter are encompassed by the former. Therefore, any restriction under 35 U.S.C. § 121 should at most be limited to a species requirement, where upon allowance of a generic claim the unexamined species may be joined for prosecution on the merits.

Applicants respectfully request rejoinder of claims 8-11 with claims 1-7 currently under examination. If rejoinder is denied for all or some of the restricted claims, Applicant respectfully requests a "second-eye review" as now implemented under the Restriction Practice Action Plan. Under the Action Plan, rejoinder practice is viewed favorably when examination of claims together would not pose a serious burden on the Examiner.

Rejection Under 35 U.S.C. § 112

Claims 1-7 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement for diagnostic methods based on IgA anti-OmpC antibodies alone. While the Office acknowledges that the application enables detection of IgA anti-OmpC antibodies together with other diagnostic markers for diagnosis of Crohn's disease, the Office Action alleges that one skilled in the art would not have been able to diagnose Crohn's disease based on the presence of

IgA anti-OmpC antibodies alone. In this regard, the Examiner emphasizes that the finding of IgA anti-OmpC antibodies in 55% of patients known to have Crohn's disease does not evidence that one skilled in the art would have been able to diagnose Crohn's disease in patients by detecting the presence or absence of IgA anti-OmpC antibodies. The Office concludes that Applicant's data fails to show a nexus between the presence of IgA anti-OmpC antibody in any population absent further conformation through the detection of other markers of Crohn's disease.

To satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *Genentech, Inc. v. Novo Nodisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997), *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998). Any use that reasonably correlates with the scope of the claim is sufficient to preclude a rejection for nonenablement. *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991). The application as filed complies with this standard.

Applicants have described and claimed a method of diagnosing Crohn's disease in a subject. The method includes determining the presence or absence of IgA anti-outer membrane protein C (anti-OmpC) antibodies in the subject, where the presence of said IgA anti-OmpC antibodies indicates that the subject has Crohn's disease.

The application teaches methods for diagnosing Crohn's disease based on detection of IgA anti-OmpC antibodies. For example, the application teaches detection of Crohn's disease based on detection of IgA anti-OmpC antibodies alone when it states:

> [As] shown in Table 2, IgA OmpC reactivity itself detected 55% of patients having Crohn's disease.

Application at page 6, lines 19-21, emphasis added.

Table 2 shows the statistical numbers from actual tests that resulted in detection of 55% of the subjects having the presence of IgA anti-OmpC and being diagnostic of Crohn's disease. These results show that anti-OmpC antibodies are present in a large subset of patients with Crohn's disease and can serve to diagnose Crohn's disease where they are present. Table 2 and

Figure 4 also show that IgA anti-OmpC antibodies were present in 56% of patients having Crohn's disease but in only 1 of 26 individuals without Crohn's disease (page 7, Table 2, and Figure 4). From these teachings in the application, it is clear that the application provides sufficient guidance to those skilled in the art to employ detection of IgA anti-OmpC antibodies in a diagnostic method for Crohn's disease.

The Office's assertion that in the absence of further confirmation using other Crohn's disease markers there is insufficient nexus between the presence of IgA anti-OmpC antibody and diagnosis of Crohn's disease is unsupported and conclusory. Applicants' have shown that more often than not the presence of IgA anti-OmpC antibody occurs in subjects with Crohn's disease. Hence, the claimed method is predictive of Crohn's disease a majority of the time (56%) and does not lead to false positives in almost all of the cases (1 out of 26 individuals). These results show a sufficient nexus between the detection of IgA anti-OmpC antibody and diagnosis of Crohn's disease.

The mere assertion by the Office that a 55% majority of subjects is insufficient to be diagnostic is conclusory. The Office appears to be holding Applicants to a higher standard than that claimed by the invention or than that required by law. The "highly sensitive" or "confirmatory" requirement the Office appears to be applying to Applicants' claimed invention appears to be a preferred or commercial standard rather than what is required based on the language of the claims. The Federal Circuit has made it clear that such a standard is in appropriate.

In *CFMT, Inc. v. Yieldup International Corp.*, the Court held semiconductor patents directed to a system for cleaning semiconductor wafers to be enabled where a prototype machine performed the claimed result, albeit not at a the level required by commercial cleanliness standards. Overturning a district court decision of invalidity, the Federal Circuit stated:

> In essence, the district court set the enablement bar too high. Enablement does not require an inventor to meet lofty standards for success in the commercial marketplace. Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.

> Title 35 requires only that the inventor enable one of skill in the art to make and use the full scope of the claimed invention. Thus, when an invention claims a general system to improve the cleaning process for semiconductor wafers, the disclosure enables that invention by showing improvements in the overall system.

349 F.3d 1333, 1338 (Fed. Cir. 2003) (emphasis added).

The Court expressly noted that if the patent in issue had claimed a system that achieved a specific level of cleanliness then enablement would require a disclosure of a method that enables the claimed level without undue experimentation. *Id.*, *citing Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1306-07 (Fed. Cir. 2001); *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Thus, in *CFMT*, enablement of the claimed invention was satisfied where the patented machine achieved the result claimed and not a higher level of performance that was beneficial to uses in the industry.

Similarly, in the subject application, the claimed invention is directed to a method of diagnosing Crohn's disease by determining the presence or absence of IgA anti-OmpC antibodies in the subject. The application teaches that a majority of the subjects with Crohn's disease exhibit the presence of IgA anti-OmpC antibodies and that almost all individuals without Crohn's disease do not have such antibodies present. The claims do not require a specified level of diagnosis nor do they recite a requirement for a confirmatory test using a second Crohn's marker. Therefore, the claims are enabled by the application sufficient for those skilled in the art to practice the invention as claimed without undue experimentation. Withdrawal of this ground of rejection is respectfully requested.

CONCLUSION

In light of the Amendments and Remarks herein, Applicants submit that the claims are in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, she is invited to call the undersigned attorney.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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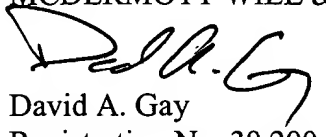

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